

REMARKS

Claims 1-14 are pending in this application.

Claim Rejections Under 35 U.S.C. 102(b):

Claims 1 and 9 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,331,538 to Higgins (hereinafter "Higgins"). The Examiner contends that Higgins discloses a syringe having a barrel, plunger and having anti-reflux means and refers Applicants to elements 20, 120, 220 and 320 in Figs. 1-9 of Higgins.

Higgins recites that there is a problem with conventional hypodermic syringes wherein the plunger sticks to the nose piece of the barrel due to formation of a vacuum between the plunger and the transverse wall of the nose piece of the barrel. To solve this problem, Higgins provides various structures to allow fluid communication between the bore at the tip of the syringe barrel and the space between the head of the plunger and the frusto-conically shaped end wall of the barrel. These structures include radial projections (Figs. 2 and 3), radial grooves (Figs. 4 and 5) and others.

The structure taught by Higgins creates the problem which the Applicants' claimed invention attempts to solve. Higgins creates structure to allow for the easy transfer of fluid between the stopper and the end of the barrel; and the bore of the barrel tip. On the other hand, the Applicants' claimed invention attempts to eliminate this type of fluid communication so that flexure of the stopper cannot cause reflux after the contents of the syringe have been delivered. Accordingly, Higgins does not have anti-reflux means in a barrel for controlling stopper deflection when fluid has been delivered from the chamber and the stopper is in contact with the distal wall of the barrel. To the contrary, Higgins provides structure which appears to have uncontrolled fluid communication and reflux between the face of the stopper and the bore of the syringe tip. Also Higgins' teaching of a plunger formed of resilient materials, such as rubber does not anticipate all the limitations of Applicants' Claim 9. It is settled case law that unless all of the same elements are found in exactly the same situation and united in the same way to perform an identical function in a single prior art reference, there can be no anticipation. Clearly there is no anticipation of the Applicants' Claims 1 and 9 which depends from Claim 1, based on the teachings of Higgins. Accordingly, based on

the arguments made hereinabove, the Applicants respectfully request withdrawal of the rejection of Claims 1 and 9 based on 35 U.S.C. 102(b) using Higgins as a reference.

Claims 6 and 10 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,899,881 to Grimard et al. The Examiner states that Grimard et al. discloses a syringe assembly having a barrel 100, plunger 116, anti-reflux means 250, needle assembly 400 and flush solution.

Applicants' Claims 6 and 10 depend from Claim 1 which requires anti-reflux means in the barrel. There is no anti-reflux means in the barrel of the syringe taught by Grimard et al. Aside from the fluid by-pass, the syringe barrel of Grimard et al. is a conventional syringe barrel with no structure to limit or prevent reflux.

"Flush Agent 'F'" referred to by Grimard et al. appears to be for removing the last remnants of reconstituted medication from the syringe and not a flushing solution for IV flush procedures as in Applicants' claims.

As indicated above, it is settled case law that unless all of the same elements are found in exactly the same situation and united the same way to perform an identical function in a single prior art reference, there is no anticipation. Clearly there is no anticipation of the Applicants' Claims 6 and 10, which depend from Claim 1, based on the teachings of Grimard et al.

Accordingly, the Applicants respectfully request withdrawal of the rejection of Claims 6 and 10 based on 35 U.S.C. 102(b) using Grimard et al as a reference.

Claim Rejections Under 35 U.S.C. 103:

Claims 2-5 and 8 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins. The Examiner states that Higgins discloses the claimed invention and suggests using the combination of projections on the stopper and the distal wall of the syringe. The Examiner further states that even though Higgins does not expressly disclose an annular boss, at the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to replace projections 20 of Higgins with the Applicants' claimed annular boss. The Examiner concludes that the Applicants have not disclosed that the annular shape provides any advantage, is used for a particular purpose, or solve the stated problem.

The Examiner concludes that one of ordinary skill in the art, would have expected the Applicants' invention to perform equally well with the projection of Higgins because both projections and an annular boss would inhibit the stopper from making full contact with the distal wall of the syringe. Therefore, it would have been an obvious matter of design choice to modify Higgins to obtain the invention as specified in Claims 2-5.

Applicants respectfully contend that the Examiner's position, stated above, is incorrect. The Applicants have disclosed that the annular shape provides an advantage, that it is used for a particular purpose and that it solves a stated problem. In particular, the claimed invention is directed toward a syringe having anti-reflux features. The annular boss is provided so that flexure of the stopper after contact with the annular boss is not translated into fluid flow in the catheter line. In particular, the Applicants state in paragraph 0024 of the application as filed, referring to Fig. 6, that "(a)t the completion of the flush procedure distal surface 59 of the stopper contacts annular boss 35, inside the area of the stopper projection, sealing the passageway so that further deflection of the stopper will have little or no effect on liquid in the passageway and the catheter." (emphasis added) The Applicants' claimed structure produces the opposite result of the teachings of Higgins which seek to promote flow of liquid into the syringe tip after medication has been delivered by providing structure that will allow the free-flow of liquid between the stopper and the distal wall of the barrel and the passageway of the barrel. Higgins does not teach or suggest anti-reflux features and in fact teaches away from such a syringe by providing structure that promotes reflux.

Further, the "at least one projection" in Applicants' Claim 5, as argued hereinafter, is not the same as Higgins' projections or recesses. Also, it cannot be seen how Higgins' teachings which do not mention any specific solution to be injected can be a basis for a rejection of Applicants' Claim 8 which recited specific flush solutions.

The Applicants contend that the basis of this rejection is picking only those parts of Higgins that will support the rejection while disregarding the teachings of Higgins directed towards a syringe having free-flow between the stopper face and the syringe tip, and the Applicants' clear teachings of anti-reflux means including an annular boss to block fluid flow to the syringe tip from the volume between the stopper face and the distal end of the syringe barrel after the stopper contacts the annular boss. Clearly the

structure of Higgins is the antithesis of the Applicants' claimed syringe having anti-reflux features.

Accordingly, based on the arguments made hereinabove, the Applicants respectfully request the withdrawal of the rejection of Claim 2,3,4,5, and 8 based on 35 U.S.C. 103(a) using Higgins as a reference.

Claims 7,11 and 12 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Higgins in view of U.S. Patent No. 6,361,524 to Odell et al (hereinafter "Odell"). The Examiner states that Higgins discloses the claimed limitations as described above but does not disclose a tip cap and that Odell teaches a cap for maintaining the sterility of the syringe contents before use and during transport.

With regard to Claim 7, the Applicants agree with the Examiner that Odell does disclose a tip cap which can be placed on a syringe. However, the syringe to which the Examiner refers is not obvious in light of the teachings of Higgins as argued hereinabove.

With regard to Claims 11 and 12, the arguments made hereinabove for overcoming the rejection to Claim 2 apply. There is no annular boss in Higgins, and the placement of such structure would make Higgins unsuited for its intended purpose. It is settled case law that a combination that results in an inoperable construction is improper for supporting a determination of obviousness. (See MPEP § 2143.02)

With regard to Claim 12, the Applicants' claimed at least one projection on the distal surface of the stopper is shaped so that upon further deflection of the stopper, after the stopper contacts the annular boss, the projection will not be able to force the stopper to move proximally, i.e., the projection cannot create enough force to move the stopper proximally to create reflux. This is exactly the opposite of the projections in Higgins which are designed to create reflux by keeping open the fluid path between the syringe tip and the volume between the stopper face and the distal wall of the barrel, and if that were not so, Higgins' structure would be inoperable for its intended purpose.

The Applicants contend to the prime facie case of obviousness has not been made for the rejection of Claims 7,11 and 12 under 35 U.S.C. 103(a). To establish a prime facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge

generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. A prime facie case of obviousness has not been established here, since Higgins fails to teach or suggest the limitations of the Applicants' claims regarding anti-reflux structure. Moreover, the features of the Applicants' claims would not have been a matter of obvious design choice, as the Examiner suggests, since features that make the Applicants' claimed invention function properly are those features that would defeat the purpose of the syringe of Higgins. Therefore, it is respectfully submitted that a 35 U.S.C. 103(a) rejection must be withdrawn with respect to Claims 7, 11 and 12.

Claims 13 and 14 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,135,489 to Jepson et al. (hereinafter "Jepson") in view of Higgins.

The Examiner states that Jepson discloses the claimed method of flushing a catheter but does not disclose a syringe having anti-reflux means. Higgins discloses such a syringe as shown above. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the invention of Jepson by including the syringe of Higgins in order to maintain positive pressure in the IV line by preventing a stopper from drawing back after injection.

Contrary to the Examiner's position, the syringe of Higgins is not intended to prevent the stopper from drawing back after injection. In fact, the primary thrust of the teachings of Higgins is to create a structure that will allow the stopper to move backwards to solve the "vexatious problem of the sticking of the plunger in the final position." (col. 4, lines 18-19) The structure of Higgins is directed toward means for breaking the seal between the plunger and the barrel as the plunger is in its final position. Structure which promotes reflux helps Higgins solve the stated problem. The Applicants' syringe provides structure in the barrel for blocking fluid flow between the volume described by the stopper face at the barrel end wall, and the syringe tip passageway. It is settled case law that references which lead substantially away from the claimed invention will not support the determination of obviousness. Here the rejection is based on picking only that part of Higgins that will support a decision of obviousness and disregarding the other parts of the reference that are necessary for a

full understanding of what the reference really suggests. The Applicants contend that the combined teachings of Higgins and Jepson cannot result in a determination that the Applicants' Claims 13 and 14 are obvious.

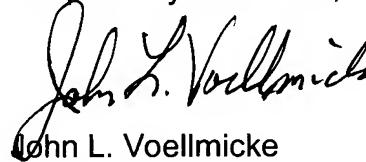
Accordingly, based on the arguments made hereinabove, the Applicants respectfully request the withdrawal of the rejection of Claims 13 and 14 under 35 U.S.C. 103(a) using Jepson and Higgins as references.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone applicant's attorney at (201) 847-7115 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 02-1666 therefor.

Respectfully submitted,



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